UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: November 7, 2017

Subject: Efficacy Review for Project Flash Spray, EPA File Symbol 9480-RU
(DP Barcode: 440588)

From: Alison Clune
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Kristen Willis, Acting Team Leader
Product Science Branch
Antimicrobials Division (7510P)

To: Zeno Bain, PM 33 / Terria Northern
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Professional Disposables International, Inc.
100 Philips Parkway
Montvale, NJ 07645

Formulation from the Label:

Active Ingredient(s)	% by wt.
Hydrogen peroxide	4.04%
Other Ingredients	95.96%
Total	100.00%

I BACKGROUND

Product Description (as packaged, as applied): Trigger spray

Submission type: New product

Requested efficacy claim(s): one-step hospital disinfectant (bactericidal, virucidal, fungicidal, tuberculocidal, sporicidal against *Clostridium difficile*); emerging viral pathogens claims against enveloped, large non-enveloped, and small non-enveloped viruses.

Documents considered in this review:

- 2 letters from applicant to EPA dated May 9, 2017 and July 17, 2017
- Proposed label PDI/9480-XX/labels/2017/9480-XX label 041817.doc, dated April 26, 2017
- 47 efficacy studies (MRID 50282509-50282555)
- Proposed Basic Confidential Statement of Formula (EPA Form 8670-4) dated 04/26/2017.

II PROPOSED DIRECTIONS FOR USE

"**TO DISINFECT [CLEAN] [AND DEODORIZE]:** Spray [*product name*] 6-8 inches from surface until thoroughly wet. Allow surface to remain [wet] [treated] for one (1) minute. For [*Clostridium difficile*] [*C. difficile*] spores, allow to remain [wet] [treated] for five (5) minutes. Let air dry [or wipe excess liquid using a towel]. [A potable water rinse is required for food contact surfaces.] If present, remove [gross filth] [and] [heavy] [soil loads] prior to disinfecting. A precleaning step is required to kill [*Clostridium difficile*] [*or C. difficile*] spores and *Mycobacterium bovis* BCG (TB)."

III STUDY SUMMARIES

Note: Three sprays of the product were applied to the inoculated surface in all 5 minute studies, while four sprays were applied to the inoculated surface in all 1 minute studies (except virus studies).

1.	**MRID**	50282509	**Study Completion Date:**			11/21/16	
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Staphylococcus aureus* (ATCC 6538)					
Test Method		AOAC Germicidal Spray Method					
Application Method		Spray					
Test Substance Preparation	**Name/ID**	Project Flash (identical to Project Flash Spray)					
	Lots ☐ 1 ☒ 2 ☐ 3	PDI-0061-LO-938-148A PDI-0061-LO-938-148C					
	Preparation	Ready to Use at LCL					
Soil load		5% Fetal Bovine Serum					
Carrier type, # per lot		Glass slides, 60					
Test conditions		**Contact time**	1 minute	**Temp**	21˚C	**RH**	43%
Testing Lab, Lab Study ID		Accuratus Lab Services, A20971					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None					

2.	MRID	50282510	Study Completion Date:	9/9/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Staphylococcus aureus* (ATCC 6538)				
Test Method		AOAC Germicidal Spray Method				
Application Method		Spray				
Test Substance Preparation	**Name/ID**	Project Flash (identical to Project Flash Spray)				
	Lots ☐ 1 ☐ 2 ☒ 3	PDI-0061-LO-938-112-A1 PDI-0061-LO-938-112-A2 PDI-0061-LO-938-112-A3				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass slides, 60				
Test conditions		**Contact time**	5 minutes	**Temp**	21.9˚C	**RH**	18%
Testing Lab, Lab Study ID		Accuratus Lab Services, A19666				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

3.	MRID	50282511	Study Completion Date:	9/9/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Pseudomonas aeruginosa* (ATCC 15442)				
Test Method		AOAC Germicidal Spray Method				
Application Method		Spray				
Test Substance Preparation	**Name/ID**	Project Flash (identical to Project Flash Spray)				
	Lots ☐ 1 ☐ 2 ☒ 3	PDI-0061-LO-938-112-A1 PDI-0061-LO-938-112-A2 PDI-0061-LO-938-112-A3				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass slides, 60				
Test conditions		**Contact time**	5 minutes	**Temp**	20.37˚C	**RH**	20.84%
Testing Lab, Lab Study ID		Accuratus Lab Services, A19665				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

4.	**MRID**	50282512	**Study Completion Date:**			11/21/16	
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Pseudomonas aeruginosa* (ATCC 15442)					
Test Method		AOAC Germicidal Spray Method					
Application Method		Spray					
Test Substance Preparation	**Name/ID**	Project Flash (identical to Project Flash Spray)					
	Lots ☐ 1 ☒ 2 ☐ 3	PDI-0061-LO-938-148A PDI-0061-LO-938-148C					
	Preparation	Ready to Use at LCL					
Soil load		5% Fetal Bovine Serum					
Carrier type, # per lot		Glass slides, 60					
Test conditions		**Contact time**	1 minute	**Temp**	20˚C	**RH**	46%
Testing Lab, Lab Study ID		Accuratus Lab Services, A20970					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None					

5.	**MRID**	50282513	**Study Completion Date:**			9/9/16	
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Salmonella enterica* (ATCC 10708)					
Test Method		AOAC Germicidal Spray Method					
Application Method		Spray					
Test Substance Preparation	**Name/ID**	Project Flash (identical to Project Flash Spray)					
	Lots ☐ 1 ☐ 2 ☒ 3	PDI-0061-LO-938-112-A1 PDI-0061-LO-938-112-A2 PDI-0061-LO-938-112-A3					
	Preparation	Ready to Use at LCL					
Soil load		5% Fetal Bovine Serum					
Carrier type, # per lot		Glass slides, 60					
Test conditions		**Contact time**	5 minutes	**Temp**	20˚C	**RH**	36%
Testing Lab, Lab Study ID		Accuratus Lab Services, A19664					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None					

6.	MRID	50282514	Study Completion Date:	11/21/16
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Salmonella enterica* (ATCC 10708)		
Test Method		AOAC Germicidal Spray Method		
Application Method		Spray		
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)		
	Lots ☐ 1 ☒ 2 ☐ 3	PDI-0061-LO-938-148A PDI-0061-LO-938-148C		
	Preparation	Ready to Use at LCL		
Soil load		5% Fetal Bovine Serum		
Carrier type, # per lot		Glass slides, 60		
Test conditions		Contact time: 1 minute	Temp: 20˚C	RH: 47%
Testing Lab, Lab Study ID		Accuratus Lab Services, A20969		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None		

7.	MRID	50282515	Study Completion Date:	1/14/16
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Multi-drug Resistant (MDR) *Acinetobacter baumannii* (ATCC 19606)		
Test Method		AOAC Germicidal Spray Method		
Application Method		Spray		
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)		
	Lots ☐ 1 ☒ 2 ☐ 3	PDI-0061-LO-938-112-A1 PDI-0061-LO-938-112-A2		
	Preparation	Ready to Use at LCL		
Soil load		5% Fetal Bovine Serum		
Carrier type, # per lot		Glass slides, 10		
Test conditions		Contact time: 5 minutes	Temp: 21.7˚C	RH: 15.2%
Testing Lab, Lab Study ID		Accuratus Lab Services, A19953		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Antibiotic sensitivity testing conducted at University of Minnesota Physicians Outreach Laboratories. Strain demonstrated resistance to gentamicin and trimethoprim/sulfa.		

8.	MRID	50282516	Study Completion Date:	12/6/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Multi-drug Resistant (MDR) *Acinetobacter baumannii* (ATCC 19606)				
Test Method		AOAC Germicidal Spray Method				
Application Method		Spray				
Test Substance Preparation	**Name/ID**	Project Flash (identical to Project Flash Spray)				
	Lots ☒ 1 ☐ 2 ☐ 3	PDI-0061-LO-938-148B				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass slides, 10				
Test conditions		**Contact time**	1 minute	**Temp**	20˚C	**RH**	54%
Testing Lab, Lab Study ID		Accuratus Lab Services, A21134				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Antibiotic sensitivity testing conducted at University of Minnesota Physicians Outreach Laboratories. Strain demonstrated resistance to gentamicin and trimethoprim/sulfa.				

9.	MRID	50282517	Study Completion Date:	9/15/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705)				
Test Method		AOAC Germicidal Spray Method				
Application Method		Spray				
Test Substance Preparation	**Name/ID**	Project Flash (identical to Project Flash Spray)				
	Lots ☐ 1 ☒ 2 ☐ 3	PDI-0061-LO-938-112-A1 PDI-0061-LO-938-112-A2				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass slides, 10				
Test conditions		**Contact time**	5 minutes	**Temp**	20˚C	**RH**	28%
Testing Lab, Lab Study ID		Accuratus Lab Services, A20022				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Antibiotic sensitivity testing conducted at Accuratus Lab Services by modified Hodge test. Strain demonstrated carbapenemase activity in the presence of meropenem.				

10.	MRID	50282518	Study Completion Date:	12/6/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705)				
Test Method		AOAC Germicidal Spray Method				
Application Method		Spray				
Test Substance Preparation	**Name/ID**	Project Flash (identical to Project Flash Spray)				
	Lots ☒ 1 ☐ 2 ☐ 3	PDI-0061-LO-938-148A				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass slides, 10				
Test conditions		**Contact time**	1 minute	**Temp**	21˚C	**RH**	51%
Testing Lab, Lab Study ID		Accuratus Lab Services, A21098				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Antibiotic sensitivity testing conducted at Accuratus Lab Services by modified Hodge test. Strain demonstrated carbapenemase activity in the presence of meropenem.				

11.	MRID	50282519	Study Completion Date:	9/15/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Extended-Spectrum beta-lactamase (ESBL) producing *Escherichia coli* (ATCC BAA-196)				
Test Method		AOAC Germicidal Spray Method				
Application Method		Spray				
Test Substance Preparation	**Name/ID**	Project Flash (identical to Project Flash Spray)				
	Lots ☐ 1 ☒ 2 ☐ 3	PDI-0061-LO-938-112-A1 PDI-0061-LO-938-112-A2				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass slides, 10				
Test conditions		**Contact time**	5 minutes	**Temp**	20˚C	**RH**	28%
Testing Lab, Lab Study ID		Accuratus Lab Services, A20020				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Antibiotic Sensitivity testing conducted at Accuratus Lab Services by Etest® assay. Strain demonstrated ESBL activity according to the Etest package insert for ceftazidime/ceftazidime + clavulanic acid.				

12.	MRID	50282520	Study Completion Date:	12/6/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Extended-Spectrum beta-lactamase (ESBL) producing *Escherichia coli* (ATCC BAA-196)				
Test Method		AOAC Germicidal Spray Method				
Application Method		Spray				
Test Substance Preparation	**Name/ID**	Project Flash (identical to Project Flash Spray)				
	Lots ☒ 1 ☐ 2 ☐ 3	PDI-0061-LO-938-148B				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass slides, 10				
Test conditions		**Contact time**	1 minute	**Temp**	20˚C	**RH**	51%
Testing Lab, Lab Study ID		Accuratus Lab Services, A21156				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Antibiotic sensitivity testing conducted at Accuratus Lab Services by Etest® assay. Strain demonstrated ESBL activity according to the Etest package insert for ceftazidime/ceftazidime + clavulanic acid.				

13.	MRID	50282521	Study Completion Date:	1/20/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Methicillin Resistant *Staphylococcus aureus* (MRSA) (ATCC 33592)				
Test Method		AOAC Germicidal Spray Method				
Application Method		Spray				
Test Substance Preparation	**Name/ID**	Project Flash (identical to Project Flash Spray)				
	Lots ☐ 1 ☒ 2 ☐ 3	PDI-0061-LO-938-112-A1 PDI-0061-LO-938-112-A2				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass slides, 10				
Test conditions		**Contact time**	5 minutes	**Temp**	22˚C	**RH**	13.7%
Testing Lab, Lab Study ID		Accuratus Lab Services, A19948				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Antibiotic sensitivity testing conducted at Accuratus Lab Services by Kirby Bauer assay. Strain demonstrated resistance to oxacillin.				

14.	MRID	50282522	Study Completion Date:	12/6/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Methicillin Resistant *Staphylococcus aureus* (MRSA) (ATCC 33592)				
Test Method		AOAC Germicidal Spray Method				
Application Method		Spray				
Test Substance Preparation	**Name/ID**	Project Flash (identical to Project Flash Spray)				
	Lots ☒ 1 ☐ 2 ☐ 3	PDI-0061-LO-938-148A				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass slides, 10				
Test conditions		**Contact time**	1 minute	**Temp**	21˚C	**RH**	49%
Testing Lab, Lab Study ID		Accuratus Lab Services, A21135				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Antibiotic sensitivity testing conducted at Accuratus Lab Services by Kirby Bauer assay. Strain demonstrated resistance to oxacillin.				

15.	MRID	50282523	Study Completion Date:	9/15/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		New Delhi metallo-beta-lactamase 1 (NDM-1) producing *Enterobacter cloacae* (CDC 1000654)				
Test Method		AOAC Germicidal Spray Method				
Application Method		Spray				
Test Substance Preparation	**Name/ID**	Project Flash (identical to Project Flash Spray)				
	Lots ☐ 1 ☒ 2 ☐ 3	PDI-0061-LO-938-112-A1 PDI-0061-LO-938-112-A2				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass slides, 10				
Test conditions		**Contact time**	5 minutes	**Temp**	20˚C	**RH**	28%
Testing Lab, Lab Study ID		Accuratus Lab Services, A20021				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Antibiotic sensitivity testing conducted at University of Minnesota Physicians Outreach Laboratories. Strain demonstrated resistance to ertapenem, imipenem, amikacin, ampicillin, ampicillin/sulbactam, cefazolin, cefepime, ceftazidime, ceftriaxone, ciprofloxacin, gentamicin, levofloxacin, piperacillin/tazo, tobramycin, trimethoprim/sulfa, and meropenem.				

16.	MRID	50282524	Study Completion Date:	12/6/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		New Delhi metallo-beta-lactamase 1 (NDM-1) producing *Enterobacter cloacae* (CDC 1000654)				
Test Method		AOAC Germicidal Spray Method				
Application Method		Spray				
Test Substance Preparation	**Name/ID**	Project Flash (identical to Project Flash Spray)				
	Lots ☒ 1 ☐ 2 ☐ 3	PDI-0061-LO-938-148B				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass slides, 10				
Test conditions		**Contact time**	1 minute	**Temp**	20˚C	**RH**	49%
Testing Lab, Lab Study ID		Accuratus Lab Services, A21155				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Antibiotic sensitivity testing conducted at University of Minnesota Physicians Outreach Laboratories. Strain demonstrated resistance to ertapenem, imipenem, amikacin, ampicillin, ampicillin/sulbactam, cefepime, ceftazidime, ceftriaxone, ciprofloxacin, gentamicin, levofloxacin, piperacillin/tazo, tobramycin, trimethoprim/sulfa, and meropenem.				

17.	MRID	50282525	Study Completion Date:	1/20/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Vancomycin resistant *Enterococcus faecalis* (VRE) (ATCC 51575)				
Test Method		AOAC Germicidal Spray Method				
Application Method		Spray				
Test Substance Preparation	**Name/ID**	Project Flash (identical to Project Flash Spray)				
	Lots ☐ 1 ☒ 2 ☐ 3	PDI-0061-LO-938-112-A1 PDI-0061-LO-938-112-A2				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass slides, 10				
Test conditions		**Contact time**	5 minutes	**Temp**	20.4˚C	**RH**	18.2%
Testing Lab, Lab Study ID		Accuratus Lab Services, A19946				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Antibiotic sensitivity testing conducted at Accuratus Lab Services by Kirby Bauer assay. Strain demonstrated resistance to vancomycin. The test culture was allowed to stand for 1 minute (as opposed to 10 minutes) between vortex mixing and removal and pooling of the upper portion of the culture for use in the test.				

18.	MRID	50282526	Study Completion Date:	12/6/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Vancomycin resistant *Enterococcus faecalis* (VRE) (ATCC 51575)				
Test Method		AOAC Germicidal Spray Method				
Application Method		Spray				
Test Substance Preparation	**Name/ID**	Project Flash (identical to Project Flash Spray)				
	Lots ☒ 1 ☐ 2 ☐ 3	PDI-0061-LO-938-148A				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass slides, 10				
Test conditions		**Contact time**	1 minute	**Temp**	21˚C	**RH**	51%
Testing Lab, Lab Study ID		Accuratus Lab Services, A21137				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Antibiotic sensitivity testing conducted at Accuratus Lab Services by Kirby Bauer assay. Strain demonstrated resistance to vancomycin.				

19.	MRID	50282527	Study Completion Date:	9/15/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Adenovirus Type 5, Strain Adenoid 75 (ATCC VR-5)				
Test Method		ASTM E1053				
Application Method		Spray				
Test Substance Preparation	**Name/ID**	Project Flash (identical to Project Flash Spray)				
	Lots ☐ 1 ☐ 2 ☒ 3	PDI-0061-LO-938-112-A1 PDI-0061-LO-938-112-A2 PDI-0061-LO-938-112-A3				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass petri dishes, 5				
Test conditions		**Contact time**	5 minutes	**Temp**	21.0˚C	**RH**	NR
Testing Lab, Lab Study ID		Accuratus Lab Services, A20043				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

NR = Not reported

20.	MRID	50282528	Study Completion Date:	11/21/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Adenovirus Type 5, Strain Adenoid 75 (ATCC VR-5)				
Test Method		ASTM E1053				
Application Method		Spray				
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)				
	Lots ☐ 1 ☒ 2 ☐ 3	PDI-0061-LO-938-148B PDI-0061-LO-938-148C				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass petri dishes, 1				
Test conditions		Contact time	1 minute	Temp	21.0°C	RH	NR
Testing Lab, Lab Study ID		Accuratus Lab Services, A21164				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

NR = Not reported

21.	MRID	50282529	Study Completion Date:	10/10/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Rhinovirus Type 1A, Strain 2060 (ATCC VR-1559)				
Test Method		ASTM E1053				
Application Method		Spray				
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)				
	Lots ☐ 1 ☒ 2 ☐ 3	PDI-0061-LO-938-112-A1 PDI-0061-LO-938-112-A2				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass petri dishes, 1				
Test conditions		Contact time	5 minutes	Temp	21.0°C	RH	NR
Testing Lab, Lab Study ID		Accuratus Lab Services, A20024				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

NR = Not reported

22.	MRID	50282530	Study Completion Date:	11/21/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Rhinovirus Type 1A, Strain 2060 (ATCC VR-1559)				
Test Method		ASTM E1053				
Application Method		Spray				
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)				
	Lots ☒ 1 ☐ 2 ☐ 3	PDI-0061-LO-938-148A				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass petri dishes, 1				
Test conditions		Contact time	1 minute	Temp	20.0˚C	RH NR
Testing Lab, Lab Study ID		Accuratus Lab Services, A21133				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

NR = Not reported

23.	MRID	50282531	Study Completion Date:	10/10/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Rotavirus, Strain WA (ATCC VR-2018)				
Test Method		ASTM E1053				
Application Method		Spray				
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)				
	Lots ☐ 1 ☒ 2 ☐ 3	PDI-0061-LO-938-112-A1 PDI-0061-LO-938-112-A2				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass petri dishes, 1				
Test conditions		Contact time	5 minutes	Temp	20.0˚C	RH NR
Testing Lab, Lab Study ID		Accuratus Lab Services, A20023				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

NR = Not reported

24.	MRID	50282532	Study Completion Date:	11/21/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Rotavirus, Strain WA (ATCC VR-2018)				
Test Method		ASTM E1053				
Application Method		Spray				
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)				
	Lots ☒ 1 ☐ 2 ☐ 3	PDI-0061-LO-938-148B				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass petri dishes, 1				
Test conditions		Contact time	1 minute	Temp	21.0˚C	RH	NR
Testing Lab, Lab Study ID		Accuratus Lab Services, A21186				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		An initial test performed on July 6, 2016 did not produce valid data due to the disruption of the indicator cell monolayer. The test was successfully repeated on July 26, 2016.				

NR = Not reported

25.	MRID	50282533	Study Completion Date:	10/10/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Herpes Simplex Virus Type 2, Strain G (ATCC VR-734)				
Test Method		ASTM E1053				
Application Method		Spray				
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)				
	Lots ☐ 1 ☒ 2 ☐ 3	PDI-0061-LO-938-112-A1 PDI-0061-LO-938-112-A2				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass petri dishes, 1				
Test conditions		Contact time	5 minutes	Temp	20.0˚C	RH	NR
Testing Lab, Lab Study ID		Accuratus Lab Services, A19992				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

NR = Not reported

26.	MRID	50282534	Study Completion Date:	11/21/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Herpes Simplex Virus Type 2, Strain G (ATCC VR-734)				
Test Method		ASTM E1053				
Application Method		Spray				
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)				
	Lots ☒ 1 ☐ 2 ☐ 3	PDI-0061-LO-938-148B				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass petri dishes, 1				
Test conditions		Contact time	1 minute	Temp	21.0˚C	RH	NR
Testing Lab, Lab Study ID		Accuratus Lab Services, A21140				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

NR = Not reported

27.	MRID	50282535	Study Completion Date:	9/15/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Influenza A Virus (H3N2), Strain A/HongKong/8/68 (ATCC VR-544)				
Test Method		ASTM E1053				
Application Method		Spray				
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)				
	Lots ☐ 1 ☒ 2 ☐ 3	PDI-0061-LO-938-112-A1 PDI-0061-LO-938-112-A2				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass petri dishes, 1				
Test conditions		Contact time	5 minutes	Temp	20.0˚C	RH	NR
Testing Lab, Lab Study ID		Accuratus Lab Services, A20058				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

NR = Not reported

28.	MRID	50282536	Study Completion Date:	11/21/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Influenza A Virus (H3N2), Strain A/HongKong/8/68 (ATCC VR-544)				
Test Method		ASTM E1053				
Application Method		Spray				
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)				
	Lots ☒ 1 ☐ 2 ☐ 3	PDI-0061-LO-938-148A				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass petri dishes, 1				
Test conditions		Contact time	1 minute	Temp	21.0°C	RH	NR
Testing Lab, Lab Study ID		Accuratus Lab Services, A21136				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

NR = Not reported

29.	MRID	50282537	Study Completion Date:	9/15/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Respiratory Syncytial Virus, Strain Long (ATCC VR-26)				
Test Method		ASTM E1053				
Application Method		Spray				
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)				
	Lots ☐ 1 ☒ 2 ☐ 3	PDI-0061-LO-938-112-A1 PDI-0061-LO-938-112-A2				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass petri dishes, 1				
Test conditions		Contact time	5 minutes	Temp	20.0°C	RH	NR
Testing Lab, Lab Study ID		Accuratus Lab Services, A20059				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

NR = Not reported

30.	MRID	50282538	Study Completion Date:	11/21/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Respiratory Syncytial Virus, Strain Long (ATCC VR-26)				
Test Method		ASTM E1053				
Application Method		Spray				
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)				
	Lots ☒ 1 ☐ 2 ☐ 3	PDI-0061-LO-938-148B				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass petri dishes, 1				
Test conditions		Contact time	1 minute	Temp	21.0˚C	RH	NR
Testing Lab, Lab Study ID		Accuratus Lab Services, A21145				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

NR = Not reported

31.	MRID	50282539	Study Completion Date:	9/15/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Feline Calicivirus, Strain F-9 (ATCC VR-782)				
Test Method		ASTM E1053				
Application Method		Spray				
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)				
	Lots ☐ 1 ☒ 2 ☐ 3	PDI-0061-LO-938-112-A1 PDI-0061-LO-938-112-A2				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass petri dishes, 2				
Test conditions		Contact time	5 minutes	Temp	20.0˚C	RH	NR
Testing Lab, Lab Study ID		Accuratus Lab Services, A20046				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

NR = Not reported

32.	MRID	50282540	Study Completion Date:	11/21/16
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Feline Calicivirus, Strain F-9 (ATCC VR-782)		
Test Method		ASTM E1053		
Application Method		Spray		
Test Substance Preparation	**Name/ID**	Project Flash (identical to Project Flash Spray)		
	Lots ☒ 1 ☐ 2 ☐ 3	PDI-0061-LO-938-148A		
	Preparation	Ready to Use at LCL		
Soil load		5% Fetal Bovine Serum		
Carrier type, # per lot		Glass petri dishes, 2		
Test conditions		**Contact time** 1 minute	**Temp** 21.0˚C	**RH** NR
Testing Lab, Lab Study ID		Accuratus Lab Services, A20967		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None		

NR = Not reported

33.	MRID	50282541	Study Completion Date:	4/25/16
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Duck Hepatitis B Virus, Strain 11/4/12 (Hepadnavirus Testing, Inc.)		
Test Method		ASTM E1053		
Application Method		Spray		
Test Substance Preparation	**Name/ID**	Project Flash (identical to Project Flash Spray)		
	Lots ☐ 1 ☒ 2 ☐ 3	PDI-0061-LO-938-112-A1 PDI-0061-LO-938-112-A2		
	Preparation	Ready to Use at LCL		
Soil load		100% Duck Serum		
Carrier type, # per lot		Glass petri dishes, 2		
Test conditions		**Contact time** 5 minutes	**Temp** 21.0˚C	**RH** NR
Testing Lab, Lab Study ID		Accuratus Lab Services, A19765		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None		

NR = Not reported

34.	MRID	50282542	Study Completion Date:	11/21/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Duck Hepatitis B Virus, Strain 11/4/12 (Hepadnavirus Testing, Inc.)				
Test Method		ASTM E1053				
Application Method		Spray				
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)				
	Lots ☒ 1 ☐ 2 ☐ 3	PDI-0061-LO-938-148A				
	Preparation	Ready to Use at LCL				
Soil load		100% Duck Serum				
Carrier type, # per lot		Glass petri dishes, 2				
Test conditions		Contact time	1 minute	Temp	20.0°C	RH NR
Testing Lab, Lab Study ID		Accuratus Lab Services, A20937				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

NR = Not reported

35.	MRID	50282543	Study Completion Date:	9/15/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Bovine Viral Diarrhea Virus, Strain Oregon C24v-genotype 1 (National Veterinary Services Laboratories)				
Test Method		ASTM E1053				
Application Method		Spray				
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)				
	Lots ☐ 1 ☒ 2 ☐ 3	PDI-0061-LO-938-112-A1 PDI-0061-LO-938-112-A2				
	Preparation	Ready to Use at LCL				
Soil load		5% Horse Serum				
Carrier type, # per lot		Glass petri dishes, 2				
Test conditions		Contact time	5 minutes	Temp	20.0°C	RH NR
Testing Lab, Lab Study ID		Accuratus Lab Services, A20045				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Indicator cell: Bovine Turbinate cells (ATCC CRL-1390) Test medium: MEM +5% non-heat inactivated Horse Serum supplemented with 10µg/mL gentamicin, 100 units/mL penicillin, 2.5µg/mL amphotericin B Neutralizer: Sephadex LH-20 gel columns Presence of the virus was verified by direct immunofluorescence assay on the final day of incubation.				

NR = Not reported

36.	MRID	50282544	Study Completion Date:	1/9/17		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Bovine Viral Diarrhea Virus, Strain NADL (American BioResearch Lab)				
Test Method		ASTM E1053				
Application Method		Spray				
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)				
	Lots ☒ 1 ☐ 2 ☐ 3	PDI-0061-LO-1003-014A				
	Preparation	Ready to Use at LCL				
Soil load		5% serum				
Carrier type, # per lot		Glass petri dishes, 2				
Test conditions		Contact time	1 minute	Temp	20°C	RH 20.7-21.6%
Testing Lab, Lab Study ID		Microbac, MicroBioTest Division,735-217				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Indicator cell: MDBK cells (ATCC CCL-22) Dilution medium: MEM + 2% Horse Serum Neutralizer: MEM + 10% Horse Serum + 0.5% polysorbate 80 + 0.1% Catalase + 0.5% $Na_2S_2O_3$ + 5% HEPES + 1% $NaHCO_3$. Report indicates Sephacryl columns may have been used, but the procedure was not clearly described.				

37.	MRID	50282545	Study Completion Date:	10/10/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Human Immunodeficiency Virus Type 1, Strain HTLV-III_B (Advanced Biotechnologies, Inc.)				
Test Method		ASTM E1053				
Application Method		Spray				
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)				
	Lots ☐ 1 ☒ 2 ☐ 3	PDI-0061-LO-938-112-A1 PDI-0061-LO-938-112-A2				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass petri dishes, 1				
Test conditions		Contact time	5 minutes	Temp	21.0°C	RH NR
Testing Lab, Lab Study ID		Accuratus Lab Services, A19993				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

NR = Not reported

38.	MRID	50282546	Study Completion Date:	11/21/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Human Immunodeficiency Virus Type 1, Strain HTLV-III_B (Advanced Biotechnologies, Inc.)				
Test Method		ASTM E1053				
Application Method		Spray				
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)				
	Lots ☒ 1 ☐ 2 ☐ 3	PDI-0061-LO-938-148B				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass petri dishes, 1				
Test conditions		Contact time	1 minute	Temp	21.0°C	RH	NR
Testing Lab, Lab Study ID		Accuratus Lab Services, A21195				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

NR = Not reported

39.	MRID	50282547	Study Completion Date:	10/12/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Mycobacterium bovis* BCG (Organon Teknika)				
Test Method		AOAC Germicidal Spray Method with appropriate elements of the AOAC Tuberculocidal Activity of Disinfectants Test				
Application Method		Spray				
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)				
	Lots ☐ 1 ☒ 2 ☐ 3	PDI-0061-LO-938-112-A1 PDI-0061-LO-938-112-A2				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass slides, 10				
Test conditions		Contact time	5 minutes	Temp	22.4°C	RH	46.8%
Testing Lab, Lab Study ID		Accuratus Lab Services, A19658				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

40.	MRID	50282548	Study Completion Date:	12/15/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Mycobacterium bovis* BCG (Organon Teknika)				
Test Method		AOAC Germicidal Spray Method with appropriate elements of the AOAC Tuberculocidal Activity of Disinfectants Test				
Application Method		Spray				
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)				
	Lots ☐ 1 ☒ 2 ☐ 3	PDI-0061-LO-938-148A PDI-0061-LO-938-148B				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass slides, 10				
Test conditions		Contact time	1 minute	Temp	21˚C	RH 47%
Testing Lab, Lab Study ID		Microbac, MicroBioTest Division, 735-203				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Test tubes used for secondary transfers (MPB, 7H9, KM) and control tubes were incubated ±1˚C outside the indicated temperature range (36±1˚C) at two points during the incubation period.				

41.	MRID	50282549	Study Completion Date:	9/15/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Trichophyton mentagrophytes* (ATCC 9533)				
Test Method		AOAC Germicidal Spray Method				
Application Method		Spray				
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)				
	Lots ☐ 1 ☒ 2 ☐ 3	PDI-0061-LO-938-112-A1 PDI-0061-LO-938-112-A2				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass slides, 10				
Test conditions		Contact time	5 minutes	Temp	21.6˚C	RH 10.4%
Testing Lab, Lab Study ID		Accuratus Lab Services, A20044				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Neutralizer: Sabouraud Dextrose Broth + 0.14% Lecithin + 1.0% Tween 80 (Primary and Secondary) Two lots of neutralizing subculture medium were used in testing, however only one lot of uninoculated medium was incubated for the neutralizing subculture medium sterility control.				

42.	MRID	50282550	Study Completion Date:	12/6/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Trichophyton mentagrophytes* (ATCC 9533)				
Test Method		AOAC Germicidal Spray Method				
Application Method		Spray				
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)				
	Lots ☒ 1 ☐ 2 ☐ 3	PDI-0061-LO-938-148A				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass slides, 10				
Test conditions		Contact time	1 minute	Temp	20.1˚C	RH 62%
Testing Lab, Lab Study ID		Accuratus Lab Services, A21064				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Neutralizer: Sabouraud Dextrose Broth + 0.07% Lecithin + 0.5% Tween 80 + 0.01% Catalase (Primary and Secondary)				

43.	MRID	50282551	Study Completion Date:	1/22/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Candida albicans* (ATCC 10231)				
Test Method		AOAC Germicidal Spray Method				
Application Method		Spray				
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)				
	Lots ☐ 1 ☒ 2 ☐ 3	PDI-0061-LO-938-112-A1 PDI-0061-LO-938-112-A2				
	Preparation	Ready to Use at LCL				
Soil load		5% Fetal Bovine Serum				
Carrier type, # per lot		Glass slides, 10				
Test conditions		Contact time	5 minutes	Temp	18.9˚C	RH 13.1%
Testing Lab, Lab Study ID		Accuratus Lab Services, A19952				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

44.	MRID	50282552	Study Completion Date:	12/6/16
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Candida albicans* (ATCC 10231)		
Test Method		AOAC Germicidal Spray Method		
Application Method		Spray		
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)		
	Lots ☒ 1 ☐ 2 ☐ 3	PDI-0061-LO-938-148B		
	Preparation	Ready to Use at LCL		
Soil load		5% Fetal Bovine Serum		
Carrier type, # per lot		Glass slides, 10		
Test conditions		Contact time: 1 minute	Temp: 20˚C	RH: 50%
Testing Lab, Lab Study ID		Accuratus Lab Services, A21138		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		The test culture was incubated for 45 hours 45 minutes instead of the 48-54 hours specified in the protocol.		

45.	MRID	50282553	Study Completion Date:	12/23/15
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Clostridium difficile* – spore form (ATCC 43598)		
Test Method		ASTM E2197		
Application Method		Liquid		
Test Substance Preparation	Name/ID	Project Flash (identical to Project Flash Spray)		
	Lots ☒ 1 ☐ 2 ☐ 3	PDI-0061-MRC-938-100A		
	Preparation	Ready to Use at LCL		
Soil load		0.25% Bovine Serum Albumin, 0.08% Bovine Mucin, and 0.35% Yeast Extract		
Carrier type, # per lot		Brushed stainless steel disks, 10 test + 3 control		
Test conditions		Contact time: 5 minutes	Temp: 21˚C	RH: 33%
Testing Lab, Lab Study ID		Accuratus Lab Services, A19459		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None		

46.	MRID	50282554	Study Completion Date:	3/28/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Clostridium difficile* – spore form (ATCC 43598)				
Test Method		ASTM E2197				
Application Method		Liquid				
Test Substance Preparation	**Name/ID**	Project Flash (identical to Project Flash Spray)				
	Lots ☒ 1 ☐ 2 ☐ 3	PDI-0061-LO-938-120-B				
	Preparation	Ready to Use at LCL				
Soil load		0.25% Bovine Serum Albumin, 0.08% Bovine Mucin, and 0.35% Yeast Extract				
Carrier type, # per lot		Brushed stainless steel disks, 10 test + 3 control				
Test conditions		**Contact time**	5 minutes	**Temp**	20˚C	**RH** 14%
Testing Lab, Lab Study ID		Accuratus Lab Services, A20101				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

47.	MRID	50282555	Study Completion Date:	10/19/16		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Clostridium difficile* – spore form (ATCC 43598)				
Test Method		ASTM E2197				
Application Method		Liquid				
Test Substance Preparation	**Name/ID**	Project Flash (identical to Project Flash Spray)				
	Lots ☒ 1 ☐ 2 ☐ 3	PDI-0061-LO-938-128A				
	Preparation	Ready to Use at LCL				
Soil load		0.25% Bovine Serum Albumin, 0.08% Bovine Mucin, and 0.35% Yeast Extract				
Carrier type, # per lot		Brushed stainless steel disks, 10 test + 3 control				
Test conditions		**Contact time**	5 minutes	**Temp**	21˚C	**RH** 22%
Testing Lab, Lab Study ID		Accuratus Lab Services, A20277				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

IV STUDY RESULTS

Disinfection – Bactericidal Efficacy

MRID	Organism	No. Exhibiting Growth/Total No. Tested			Average log_{10} CFU/Carrier
		PDI-0061-LO-938-112-A1	PDI-0061-LO-938-112-A2	PDI-0061-LO-938-112-A3	
5 minute contact time, RTU, 5% soil load					
50282510	*Staphylococcus aureus* (ATCC 6538)	0/60	0/60	0/60	5.61
50282511	*Pseudomonas aeruginosa* (ATCC 15442)	0/60	0/60	0/60	5.63
50282513	*Salmonella enterica* (ATCC 10708)	0/60	0/60	0/60	4.38
50282515	Multi-drug Resistant (MDR) *Acinetobacter baumannii* (ATCC 19606)	0/10	0/10	--	5.69
50282517	Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705)	0/10	0/10	--	4.97
50282519	Extended-Spectrum beta-lactamase (ESBL) producing *Escherichia coli* (ATCC BAA-196)	0/10	0/10	--	6.12
50282521	Methicillin Resistant *Staphylococcus aureus* (MRSA) (ATCC 33592)	0/10	0/10	--	4.86
50282523	New Delhi metallo-beta-lactamase 1 (NDM-1) producing *Enterobacter cloacae* (CDC 1000654)	0/10	0/10	--	6.24

MRID	Organism	No. Exhibiting Growth/Total No. Tested			Average log_{10} CFU/Carrier
		PDI-0061-LO-938-112-A1	PDI-0061-LO-938-112-A2	PDI-0061-LO-938-112-A3	
5 minute contact time, RTU, 5% soil load					
50282525	Vancomycin resistant *Enterococcus faecalis* (VRE) (ATCC 51575)	0/10	0/10	--	4.83

MRID	Organism	No. Exhibiting Growth/Total No. Tested			Average log_{10} CFU/Carrier
		PDI-0061-LO-938-148A	PDI-0061-LO-938-148B	PDI-0061-LO-938-148C	
1 minute contact time, RTU, 5% soil load					
50282509	*Staphylococcus aureus* (ATCC 6538)	0/60	--	0/60	5.57
50282512	*Pseudomonas aeruginosa* (ATCC 15442)	0/60	--	0/60	5.72
50282514	*Salmonella enterica* (ATCC 10708)	0/60	--	0/60	5.34
50282516	Multi-drug Resistant (MDR) *Acinetobacter baumannii* (ATCC 19606)	--	0/10	--	5.49
50282518	Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705)	0/10	--	--	5.19
50282520	Extended-Spectrum beta-lactamase (ESBL) producing *Escherichia coli* (ATCC BAA-196)	--	0/10	--	4.87
50282522	Methicillin Resistant *Staphylococcus aureus* (MRSA) (ATCC 33592)	0/10	--	--	4.84

MRID	Organism	No. Exhibiting Growth/Total No. Tested			Average log_{10} CFU/Carrier
		PDI-0061-LO-938-148A	PDI-0061-LO-938-148B	PDI-0061-LO-938-148C	
1 minute contact time, RTU, 5% soil load					
50282524	New Delhi metallo-beta-lactamase 1 (NDM-1) producing *Enterobacter cloacae* (CDC 1000654)	--	0/10	--	6.26
50282526	Vancomycin resistant *Enterococcus faecalis* (VRE) (ATCC 51575)	0/10	--	--	5.02

Disinfection – Virucidal Efficacy

Organism	Adenovirus Type 5, Strain Adenoid 75 (ATCC VR-5)															
MRID	**Description**	**Results**														**Dried Virus Control (Log_{10} $TCID_{50}$/carrier)**
5 minutes, RTU, 5% soil load																
50282527	Lot	**PDI-0061-LO-938-112-A1**					**PDI-0061-LO-938-112-A2**					**PDI-0061-LO-938-112-A3**				6.98*
	Replicate	*1*	*2*	*3*	*4*	*5*	*1*	*2*	*3*	*4*	*5*	*1*	*2*	*3*	*4*	*5*	
	10^{-1} dilution	T	T	0	0	0	T	T	T	T	0	T	0	0	0	0	
	10^{-2} to 10^{-8} dilution	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	Maximum Log_{10} $TCID_{50}$/carrier	≤1.50					≤1.50					≤1.50					
	Minimum Log Reduction	≥5.48					≥5.48					≥5.48					
1 minute, RTU, 5% soil load																
50282528	Lot	**PDI-0061-LO-938-148B**					**PDI-0061-LO-938-148C**									8.00
	10^{-1} dilution	T					T									
	10^{-2} to 10^{-8} dilution	0					0									
	Log_{10} $TCID_{50}$/carrier	≤2.50**					≤1.50									
	Log Reduction	≥5.50					≥6.50									

T = Cytotoxicity; 0 = Complete inactivation

*Average of 5 replicates
**Cytotoxicity was observed at the 10^{-2} dilution in the cytotoxicity and neutralization confirmation controls, but not in the test.

MRID	Organism	Description	Results		Dried Virus Control (Log_{10} $TCID_{50}$/carrier)
			PDI-0061-LO-938-112-A1	PDI-0061-LO-938-112-A2	
5 minutes, RTU, 5% soil load					
50282529	Rhinovirus Type 1A, Strain 2060 (ATCC VR-1559)	10^{-1} dilution	Complete inactivation	Cytotoxicity	5.00
		10^{-2} to 10^{-8} dilution	Complete inactivation	Complete inactivation	
		Log_{10} $TCID_{50}$/carrier	≤1.50*	≤1.50	
		Log Reduction	≥3.50	≥3.50	
50282531	Rotavirus, Strain WA (ATCC VR-2018)	10^{-1} to 10^{-8} dilution	Complete inactivation	Complete inactivation	5.50
		Log_{10} $TCID_{50}$/carrier	≤0.50	≤0.50	
		Log Reduction	≥5.00	≥5.00	
50282533	Herpes Simplex Virus Type 2, Strain G (ATCC VR-734)	10^{-1} to 10^{-7} dilution	Complete inactivation	Complete inactivation	4.50
		Log_{10} $TCID_{50}$/carrier	≤0.50	≤0.50	
		Log Reduction	≥4.00	≥4.00	
50282535	Influenza A Virus (H3N2), Strain A/HongKong/8/68 (ATCC VR-544)	10^{-1} to 10^{-8} dilution	Complete inactivation	Complete inactivation	5.00
		Log_{10} $TCID_{50}$/carrier	≤1.50*	≤1.50*	
		Log Reduction	≥3.50	≥3.50	
50282537	Respiratory Syncytial Virus, Strain Long (ATCC VR-26)	10^{-1} dilution	Cytotoxicity	Complete inactivation	4.75
		10^{-2} to 10^{-7} dilution	Complete inactivation	Complete inactivation	
		Log_{10} $TCID_{50}$/carrier	≤1.50	≤1.50*	
		Log Reduction	≥3.25	≥3.25	
50282545	Human Immunodeficiency Virus Type 1, Strain $HTLV\text{-}III_B$ (Advanced	10^{-1} dilution	Cytotoxicity	Cytotoxicity	5.50
		10^{-2} to 10^{-7} dilution	Complete inactivation	Complete inactivation	
		Log_{10} $TCID_{50}$/carrier	≤1.50	≤1.50	

MRID	Organism	Description	Results				Dried Virus Control (Log_{10} $TCID_{50}$/carrier)	
			PDI-0061-LO-938-112-A1		PDI-0061-LO-938-112-A2			
5 minutes, RTU, 5% soil load								
	Biotechnologies, Inc.)	Log Reduction	≥4.00		≥4.00			
50282539	Feline Calicivirus, Strain F-9 (ATCC VR-782)	*Replicate*	*1*	*2*	*1*	*2*	*1*	*2*
		10^{-1} dilution	T	T	T	T	5.79356	6.05894
		10^{-2} dilution	T	0	T	T		
		10^{-3} to 10^{-4} dilution	0	0	0	0		
		Log_{10} $TCID_{50}$/carrier	≤2.50		≤2.50			
		Log Reduction (MPN)	≥3.55					
50282541	Duck Hepatitis B Virus, Strain 11/4/12 (Hepadnavirus Testing, Inc.)	*Replicate*	*1*	*2*	*1*	*2*	*1*	*2*
		10^{-1} to 10^{-4} dilution	0	0	0	0	5.55827	5.05894
		Log_{10} $TCID_{50}$/carrier	≤0.50		≤0.50			
		Log Reduction (MPN)	≥5.31					
50282543	Bovine Viral Diarrhea Virus, Strain Oregon C24v-genotype 1 (National Veterinary Services Laboratories)	*Replicate*	*1*	*2*	*1*	*2*	*1*	*2*
		10^{-1} dilution	0	0	T	T	4.55828	4.79357
		10^{-2} to 10^{-4} dilution	0	0	0	0		
		Log_{10} $TCID_{50}$/carrier	≤0.50		≤1.50			
		Log Reduction (MPN)	≥3.96					

T = Cytotoxicity; 0 = Complete inactivation

*Cytotoxicity was observed at the 10^{-1} dilution in the cytotoxicity and neutralization confirmation controls, but not in the test.

MRID	Organism	Description	Results		Dried Virus Control (Log_{10} $TCID_{50}$/carrier)
			PDI-0061-LO-938-148A	PDI-0061-LO-938-148B	
1 minute, RTU, 5% soil load					
50282530	Rhinovirus Type 1A, Strain 2060 (ATCC VR-1559)	10^{-1} dilution	Cytotoxicity	--	5.50
		10^{-2} to 10^{-8} dilution	Complete inactivation	--	
		Log_{10} $TCID_{50}$/carrier	≤1.50	--	
		Log Reduction	≥4.00	--	
50282532	Rotavirus, Strain WA (ATCC VR-2018)	10^{-1} dilution	--	Cytotoxicity	6.50
		10^{-2} to 10^{-8} dilution	--	Complete inactivation	
		Log_{10} $TCID_{50}$/carrier	--	≤1.50	
		Log Reduction	--	≥5.00	
50282534	Herpes Simplex Virus Type 2, Strain G (ATCC VR-734)	10^{-1} to 10^{-8} dilution	--	Complete inactivation	5.25
		Log_{10} TCID/carrier	--	≤0.50	
		Log Reduction	--	≥4.75	
50282536	Influenza A Virus (H3N2), Strain A/HongKong/8/68 (ATCC VR-544)	10^{-1} dilution	Cytotoxicity	--	4.50
		10^{-2} to 10^{-8} dilution	Complete inactivation	--	
		Log_{10} $TCID_{50}$/carrier	≤1.50	--	
		Log Reduction	≥3.00	--	
50282538	Respiratory Syncytial Virus, Strain Long (ATCC VR-26)	10^{-1} dilution	--	Cytotoxicity	5.00
		10^{-2} to 10^{-6} dilution	--	Complete inactivation	
		Log_{10} $TCID_{50}$/carrier	--	≤1.50	
		Log Reduction	--	≥3.50	
50282546	Human Immunodeficiency Virus Type 1, Strain $HTLV\text{-}III_B$ (Advanced Biotechnologies, Inc.)	10^{-1} to 10^{-2} dilution	--	Cytotoxicity	5.50
		10^{-3} to 10^{-7} dilution	--	Complete inactivation	
		Log_{10} $TCID_{50}$/carrier	--	≤2.50	
		Log Reduction	--	≥3.00	
50282540		*Replicate*	*1* *2*	--	*1* *2*

MRID	Organism	Description	Results			Dried Virus Control (Log_{10} $TCID_{50}$/carrier)	
			PDI-0061-LO-938-148A		PDI-0061-LO-938-148B		
1 minute, RTU, 5% soil load							
	Feline Calicivirus, Strain F-9 (ATCC VR-782)	10^{-1} to 10^{-4} dilution	0	0	--	5.79356	6.37893
		Log_{10} $TCID_{50}$/carrier	≤0.50		--		
		Log Reduction (MPN)	>6.09		--		
50282542	Duck Hepatitis B Virus, Strain 11/4/12 (Hepadnavirus Testing, Inc.)	*Replicate*	*1*	*2*	--	*1*	*2*
		10^{-1} to 10^{-4} dilution	0	0	--	5.37983	5.05894
		Log_{10} $TCID_{50}$/carrier	≤0.50		--		
		Log Reduction (MPN)	≥5.22		--		
50282544	Bovine Viral Diarrhea Virus, Strain Oregon C24v-genotype 1 (National Veterinary Services Laboratories)	Lot	**PDI-0061-LO-1003-014A**				
		Replicate	*1*	*2*		*1*	*2*
		10^{-2} to 10^{-3} dilution	T	T		7.67	7.55
		10^{-4} to 10^{-7} dilution	0	0			
		Log_{10} $TCID_{50}$/carrier	≤4.42				
		Log Reduction (MPN)	≥3.19				

T = Cytotoxicity; 0 = Complete inactivation

Disinfection – Tuberculocidal Efficacy, *Mycobacterium bovis* BCG (Organon Teknika)

MRID	Lot	Medium			Carrier Control Count (Average CFU/Carrier)
		MPB	7H9	KM	
5 minute contact time, 5% soil load, 90 day incubation					
50282547	**PDI-0061-LO-938-112-A1**	0/10	0/10	0/10	5.60
	PDI-0061-LO-938-112-A2	0/10	0/10	0/10	
1 minute contact time, 5% soil load, 90 day incubation					
50282548	**PDI-0061-LO-938-148A**	0/10	0/10	0/10	5.04
	PDI-0061-LO-938-148B	0/10	0/10	0/10	

Disinfection – Fungicidal Efficacy

MRID (Test Date)	Organism	No. Exhibiting Growth/Total No. Tested		Average log_{10} CFU/Carrier
		PDI-0061-LO-938-112-A1	PDI-0061-LO-938-112-A2	
5 minute contact time, RTU, 5% soil load				
50282549	*Trichophyton mentagrophytes* (ATCC 9533)	1˚ = 0/10 2˚ = 0/10	1˚ = 0/10 2˚ = 0/10	5.12
50282551 (12/31/15)	*Candida albicans* (ATCC 10231)	0/10	0/10	<3.30*
(1/12/16)		0/10	0/10	4.27

*Test was repeated due to a carrier population control failure.

MRID	Organism	No. Exhibiting Growth/Total No. Tested		Average log_{10} CFU/Carrier
		PDI-0061-LO-938-148A	PDI-0061-LO-938-148B	
1 minute contact time, RTU, 5% soil load				
50282550	*Trichophyton mentagrophytes* (ATCC 9533)	1˚ = 0/10 2˚ = 0/10	--	4.99
50282552	*Candida albicans* (ATCC 10231)	--	0/10	4.77

Disinfection - Sporicidal Efficacy – Spores of *Clostridium difficile* (ATCC 43598)

MRID	50282553	50282554	50282555
Spore titer (spores/mL)	5.3×10^8	7.1×10^8	7.1×10^8
Spore purity	99%	99%	99%
Acid resistance (log reduction)	0.73	0.66	0.66
Batch	**PDI-0061-MRC-938-100A**	**PDI-0061-LO-938-120-B**	**PDI-0061-LO-938-128A**
Test Date	10/22/15	1/20/16	2/16/16
5 minute contact time, RTU, 3-part soil load			
Control Average Log_{10} CFU/carrier	6.26	6.40	6.36
Test Average Log_{10} CFU/carrier	<0.00	<0.17	<0.29*
Log reduction	>6.26	>6.23	>6.07

*Values for geometric mean of test carriers and average log_{10} are reversed in test report.

V STUDY CONCLUSIONS

MRIDs	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	# Lots	Organism(s)	Data support tested conditions?
50282510 50282511 50282513	Disinfectant, bactericidal	Hard, non-porous surfaces	Spray, RTU	5 minutes	5%	3	• *Staphylococcus aureus* (ATCC 6538) • *Pseudomonas aeruginosa* (ATCC 15442) • *Salmonella enterica* (ATCC 10708)	**Yes**
50282515 50282517 50282519 50282521 50282523 50282525	Disinfectant, bactericidal	Hard, non-porous surfaces	Spray, RTU	5 minutes	5%	2	• Multi-drug Resistant (MDR) *Acinetobacter baumannii* (ATCC 19606) • Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705) • Extended-Spectrum beta-lactamase (ESBL) producing *Escherichia coli* (ATCC BAA-196) • Methicillin Resistant *Staphylococcus aureus* (MRSA) (ATCC 33592)\ • New Delhi metallo-beta-lactamase 1 (NDM-1) producing *Enterobacter cloacae* (CDC 1000654) • Vancomycin resistant *Enterococcus faecalis* (VRE) (ATCC 51575)	**Yes**

MRIDs	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	# Lots	Organism(s)	Data support tested conditions?
50282509 50282512 50282514	Disinfectant, bactericidal	Hard, non-porous surfaces	Spray, RTU	1 minute	5%	2	• *Staphylococcus aureus* (ATCC 6538) • *Pseudomonas aeruginosa* (ATCC 15442) • *Salmonella enterica* (ATCC 10708)	**Yes**
50282516 50282518 50282520 50282522 50282524 50282526	Disinfectant, bactericidal	Hard, non-porous surfaces	Spray, RTU	1 minute	5%	1	• Multi-drug Resistant (MDR) *Acinetobacter baumannii* (ATCC 19606) • Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705) • Extended-Spectrum beta-lactamase (ESBL) producing *Escherichia coli* (ATCC BAA-196) • Methicillin Resistant *Staphylococcus aureus* (MRSA) (ATCC 33592) • New Delhi metallo-beta-lactamase 1 (NDM-1) producing *Enterobacter cloacae* (CDC 1000654) • Vancomycin resistant *Enterococcus faecalis* (VRE) (ATCC 51575)	**Yes**
50282527	Disinfectant, virucidal	Hard, non-porous surfaces	Spray, RTU	5 minutes	5%	3	• Adenovirus Type 5, Strain Adenoid 75 (ATCC VR-5)	**Yes**

MRIDs	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	# Lots	Organism(s)	Data support tested conditions?
50282529 50282531 50282533 50282535 50282537 50282539 50282541 50282543 50282545	Disinfectant, virucidal	Hard, non-porous surfaces	Spray, RTU	5 minutes	5%	2	• Rhinovirus Type 1A, Strain 2060 (ATCC VR-1559) • Rotavirus, Strain WA (ATCC VR-2018) • Herpes Simplex Virus Type 2, Strain G (ATCC VR-734) • Influenza A Virus (H3N2), Strain A/HongKong/8/68 (ATCC VR-544) • Respiratory Syncytial Virus, Strain Long (ATCC VR-26) • Feline Calicivirus, Strain F-9 (ATCC VR-782) • Duck Hepatitis B Virus, Strain 11/4/12 (Hepadnavirus Testing, Inc.) • Bovine Viral Diarrhea Virus, Strain Oregon C24v-genotype 1 (National Veterinary Services Laboratories) • Human Immunodeficiency Virus Type 1, Strain HTLV-III_B (Advanced Biotechnologies, Inc.)	**Yes**
50282528	Disinfectant, virucidal	Hard, non-porous surfaces	Spray, RTU	1 minute	5%	2	• Adenovirus Type 5, Strain Adenoid 75 (ATCC VR-5)	**Yes**

MRIDs	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	# Lots	Organism(s)	Data support tested conditions?
50282530 50282532 50282534 50282536 50282538 50282540 50282542 50282546	Disinfectant, virucidal	Hard, non-porous surfaces	Spray, RTU	1 minute	5%	1	• Rhinovirus Type 1A, Strain 2060 (ATCC VR-1559) • Rotavirus, Strain WA (ATCC VR-2018) • Herpes Simplex Virus Type 2, Strain G (ATCC VR-734) • Influenza A Virus (H3N2), Strain A/HongKong/8/68 (ATCC VR-544) • Respiratory Syncytial Virus, Strain Long (ATCC VR-26) • Feline Calicivirus, Strain F-9 (ATCC VR-782) • Duck Hepatitis B Virus, Strain 11/4/12 (Hepadnavirus Testing, Inc.) • Human Immunodeficiency Virus Type 1, Strain HTLV-III_B (Advanced Biotechnologies, Inc.)	**Yes**
50282544	Disinfectant, virucidal	Hard, non-porous surfaces	Spray, RTU	1 minute	5%	1	• Bovine Viral Diarrhea Virus, Strain NADL (American BioResearch Lab)	**No**[1]
50282549 50282551	Disinfectant, fungicidal	Hard, non-porous surfaces	Spray, RTU	5 minutes	5%	2	• *Trichophyton mentagrophytes* (ATCC 9533) • *Candida albicans* (ATCC 10231)	**Yes**

MRIDs	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	# Lots	Organism(s)	Data support tested conditions?
50282550 50282552	Disinfectant, fungicidal	Hard, non-porous surfaces	Spray, RTU	1 minute	5%	1	• *Trichophyton mentagrophytes* (ATCC 9533) • *Candida albicans* (ATCC 10231)	**Yes**
50282547	Disinfectant, tuberculocidal	Hard, non-porous surfaces	Spray, RTU	5 minutes	5%	2	• *Mycobacterium bovis* BCG (Organon Teknika)	**Yes**
50282548	Disinfectant, tuberculocidal	Hard, non-porous surfaces	Spray, RTU	1 minute	5%	2	• *Mycobacterium bovis* BCG (Organon Teknika)	**Yes**
50282553 50282554 50282555	Disinfectant with sporicidal activity	Hard, non-porous surfaces	Spray, RTU	5 minutes	5%	3	• *Clostridium difficile* – spore form (ATCC 43598)	**Yes**

1. The study report did not clearly describe the neutralization procedure, particularly the use of Sephacryl columns. In addition, a high level of cytotoxicity was observed (out to the 10^{-3} dilution), which prevents observation of test substance efficacy in several serial dilutions. As a batch replication study, the study is not supported by the tested conditions in MRID 50282543 because a different strain of the virus was used in testing, and several conditions of testing were changed between the two studies including the neutralization procedure, indicator cell type, and test medium.

VI LABEL COMMENTS

Label Date/Identification Number: Proposed label PDI/9480-XX/labels/2017/9480-XX label 041817.doc, dated April 26, 2017

1. The proposed label claims that the ready-to-use spray product, Project Flash Spray, is an effective hospital disinfectant with bactericidal activity in the presence of 5% organic soil on hard, non-porous surfaces at a 1 minute contact time against the following:

   Staphylococcus aureus (ATCC 6538)
   Pseudomonas aeruginosa (ATCC 15442)
   Salmonella enterica (ATCC 10708)
   Multi-drug Resistant (MDR) *Acinetobacter baumannii* (ATCC 19606)
   Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705)
   Extended-Spectrum beta-lactamase (ESBL) producing *Escherichia coli* (ATCC BAA-196)
   Methicillin Resistant *Staphylococcus aureus* (MRSA) (ATCC 33592)
   New Delhi metallo-beta-lactamase 1 (NDM-1) producing *Enterobacter cloacae* (CDC 1000654)
   Vancomycin resistant *Enterococcus faecalis* (VRE) (ATCC 51575)

   These claims are **acceptable** as they are supported by the submitted data.

2. The proposed label claims that the ready-to-use spray product, Project Flash Spray, is an effective hospital disinfectant with virucidal activity in the presence of 5% organic soil on hard, non-porous surfaces at a 1 minute contact time against the following:

   Adenovirus Type 5, Strain Adenoid 75 (ATCC VR-5)
   Rhinovirus Type 1A, Strain 2060 (ATCC VR-1559)
   Rotavirus, Strain WA (ATCC VR-2018)
   Herpes Simplex Virus Type 2, Strain G (ATCC VR-734)
   Influenza A Virus (H3N2), Strain A/HongKong/8/68 (ATCC VR-544)
   Respiratory Syncytial Virus, Strain Long (ATCC VR-26)
   Feline Calicivirus, Strain F-9 (ATCC VR-782), surrogate for Norovirus
   Duck Hepatitis B Virus, Strain 11/4/12 (Hepadnavirus Testing, Inc.), surrogate for Human Hepatitis B Virus
   Human Immunodeficiency Virus Type 1, Strain HTLV-III_B (Advanced Biotechnologies, Inc.)

   These claims are **acceptable** as they are supported by the submitted data.

3. The proposed label claims that the ready-to-use spray product, Project Flash Spray, is an effective hospital disinfectant with virucidal activity in the presence of 5% organic soil on hard, non-porous surfaces at a 1 minute contact time against the following:

   Bovine Viral Diarrhea Virus, Strain Oregon C24v-genotype 1 (National Veterinary Services Laboratories), surrogate for Human Hepatitis C Virus

   These claims are **not acceptable** based on the submitted data. Claims and directions for use against this organism or the organism for which it is a surrogate should be removed or changed to a 5-minute contact time.

The complete study described in MRID 50282543 supports the proposed label claim at a 5 minute contact time, however the batch replication study described in MRID 50282544 does not support the same claim at a 1 minute contact time. The study report in MRID 50282544 did not clearly describe the neutralization procedure, particularly the use of Sephacryl columns. In addition, a high level of cytotoxicity was observed (out to the 10^{-3} dilution), which prevents observation of test substance efficacy in several serial dilutions. As a batch replication study, the study is not supported by the tested conditions in MRID 50282543 because a different strain of the virus was used in testing, and several conditions of testing were changed between the two studies including the neutralization procedure, indicator cell type, and test medium.

4. The proposed label claims that the ready-to-use spray product, Project Flash Spray, is an effective hospital disinfectant with fungicidal activity in the presence of 5% organic soil on hard, non-porous surfaces at a 1 minute contact time against the following:

   Trichophyton interdigitale, tested as *Trichophyton mentagrophytes* (ATCC 9533)
   Candida albicans (ATCC 10231)

   These claims are **acceptable** as they are supported by the submitted data.

5. The proposed label claims that the ready-to-use spray product, Project Flash Spray, is an effective hospital disinfectant with tuberculocidal activity in the presence of 5% organic soil on hard, non-porous surfaces at a 1 minute contact time against the following:

   Mycobacterium bovis BCG (Organon Teknika)

   These claims are **acceptable** as they are supported by the submitted data.

6. The proposed label claims that the ready-to-use spray product, Project Flash Spray, is an effective hospital disinfectant with sporicidal activity in the presence of 5% organic soil on hard, non-porous surfaces at a 5 minute contact time against the following:

   Clostridium difficile – spore form (ATCC 43598)

   These claims are **acceptable** as they are supported by the submitted data.

7. The proposed label claims that the product, Project Flash Spray, qualifies for the following emerging viral pathogens claims as described in the letter from the applicant to EPA dated July 17, 2017:

For an emerging viral pathogen that is a/an…	*…follow the directions for use for the following organisms on the label:*
Enveloped virus	**One** of the following: Adenovirus Type 5, Strain Adenoid 75 (ATCC VR-5) Rotavirus, Strain WA (ATCC VR-2018) Rhinovirus Type 1A, Strain 2060 (ATCC VR-1559) Feline Calicivirus, Strain F-9 (ATCC VR-782)
Large, non-enveloped virus	**One** of the following: Rhinovirus Type 1A, Strain 2060 (ATCC VR-1559) Feline Calicivirus, Strain F-9 (ATCC VR-782)
Small, non-enveloped virus	**Two** of the following: Rhinovirus Type 1A, Strain 2060 (ATCC VR-1559) Feline Calicivirus, Strain F-9 (ATCC VR-782)

These claims are **acceptable, however** the following changes should be made to the supporting documentation:

Label: The language on page 7 of the proposed label and should be revised to exactly match the following:

"**Emerging Viral Pathogens Claims**

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

- Enveloped Viruses
- Large, Non-Enveloped Viruses
- Small, Non-Enveloped Viruses

For an emerging viral pathogen that is a/an…	*…follow the directions for use for the following organisms on the label:*
Enveloped virus	Adenovirus Type 5, Strain Adenoid 75 (ATCC VR-5) Rotavirus, Strain WA (ATCC VR-2018) Rhinovirus Type 1A, Strain 2060 (ATCC VR-1559) Feline Calicivirus, Strain F-9 (ATCC VR-782)
Large, non-enveloped virus	Rhinovirus Type 1A, Strain 2060 (ATCC VR-1559) Feline Calicivirus, Strain F-9 (ATCC VR-782)
Small, non-enveloped virus	Rhinovirus Type 1A, Strain 2060 (ATCC VR-1559) Feline Calicivirus, Strain F-9 (ATCC VR-782)

Acceptable claim language:

[Product name] *has demonstrated effectiveness against viruses similar to* ***[name of emerging virus]*** *on hard,* ***[porous and/or non-porous surfaces]****. Therefore,* ***[product name]*** *can be used against* ***[name of emerging virus]*** *when used in accordance with the directions for use against* ***[name of supporting virus(es)]*** *on* ***[hard, porous/non-porous surfaces]****. Refer to the* ***[CDC or OIE]*** *website at* ***[pathogen-specific website address]*** *for additional information.*

[Name of illness/outbreak] *is caused by* ***[name of emerging virus]. [Product name]*** *kills similar viruses and therefore can be used against* ***[name of emerging virus]*** *when used in accordance with the directions for use against* ***[name of supporting virus(es)]*** *on* ***[hard, porous/non-porous surfaces]****. Refer to the* ***[CDC or OIE]*** *website at* ***[website address]*** *for additional information."*

Terms of Registration Letter: The letter from the applicant to EPA dated July 17, 2017 should be revised to include:

- All the terms of registration described in Attachment 1 of EPA's emerging viral pathogens guidance (see page 6). The language in the letter should exactly match the four numbered paragraphs in the guidance, except where the product name and/or surface type can be more specific.
- The above table of emerging virus types and corresponding supporting viruses on the label. Enveloped viruses should not appear in the terms of registration letter as tested viruses must be large or small non-enveloped viruses to support claims against emerging pathogens (see Section III on page 3 of the guidance).

8. Make the following changes to the proposed label:
   a. Throughout the label:
      i. Per Label Comment 3, remove claims and directions for use against Bovine Viral Diarrhea Virus and Human Hepatitis C Virus or change the contact time to 5 minutes for these organisms.
   b. Pages 2-4:
      i. Remove "[treated]" from all directions for use and specify the surface should remain visibly wet throughout the contact time.

c. Page 4:
   i. Specify hard, non-porous surfaces for the "Areas of Use" section.
d. Page 6:
   i. Change "Multi-Drug" to "Antibiotic" in the heading "Multi-Drug Resistant Bacteria." Not all of the listed organisms are considered multi-drug resistant.
e. Page 7:
   i. Change "Herpes Simplex type 2" to "Herpes Simplex Virus type 2."
   ii. Remove specific claims against Pandemic 2009 H1N1 Influenza A virus. This product was not tested against this virus, although it is commercially available for efficacy testing
f. Page 8:
   i. Remove "[Herpicidal*]." The agency has not defined this term.
   ii. Change "99.99%" to "99.9%." The studies supporting claims against bacteria were qualitative studies that do not provide an exact quantitative measure of organism reduction and thus do not support a 4-log (99.99%) reduction in the numbers of these organisms.
   iii. Remove "[tough-to-kill]."
   iv. Remove "bathroom" from the claim "Effective against bathroom bacteria and viruses" or revise the claim. The agency has not defined "bathroom" organisms.
g. Page 9:
   i. Remove "[Herpicidal*]." See Label Comment 8.f.i.
   ii. Remove "[quickly] [fast]." These terms only apply to products that are effective in 30 seconds or less.
   iii. Remove the claim "[Kills] [Effective against] ESKAPE bacteria [in 1 [one] minute]." *Enterococcus faecium* is one of the ESKAPE bacteria, but does not appear on the label (*Enterococcus faecalis* is a different organism.)
   iv. Remove "[household] [exterior toilet surface] [bathroom]" from the claim "Kills [household] [exterior toilet surface] [bathroom] germs" or revise the claim. The agency has not defined "household", "exterior toilet surface", or "bathroom" organisms.
h. Page 10:
   i. Change "Surface disinfectant" to "Hard, non-porous surface disinfectant."